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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
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09/422,999 10/22/99 KAWASAKI H MIT-103

021323 HM22/0510  
TESTA HURWITZ & THIBEAULT  
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125 HIGH STREET  
BOSTON MA 02110

EXAMINER

MURPHY, J

ART UNIT

PAPER NUMBER

1644

DATE MAILED:

05/10/00

**Please find below and/or attached an Office communication concerning this application or proceeding.**

**Commissioner of Patents and Trademarks**

**Office Action Summary**

Application No.

09/422,999

Applicant(s)

KAWASAKI ET AL.

Examiner

Joseph F Murphy

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-- The MAILING DATE of this communication appears in the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).

**Status**

- 1) ☒ Responsive to communication(s) filed on 22 October 1999.
- 2a) ☐ This action is **FINAL**.                      2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-130 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☐ Claim(s) \_\_\_\_\_ is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☒ Claims 1-130 are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are objected to by the Examiner.
- 11) ☐ The proposed drawing correction filed on \_\_\_\_\_ is: a) ☐ approved b) ☐ disapproved.
- 12) ☐ The oath or declaration is objected to by the Examiner.

**Priority under 35 U.S.C. § 119**

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).
- a) ☐ All b) ☐ Some \* c) ☐ None of the CERTIFIED copies of the priority documents have been:
1. ☐ received.
2. ☐ received in Application No. (Series Code / Serial Number) \_\_\_\_\_.
3. ☐ received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. & 119(e).

**Attachment(s)**

- 14) ☐ Notice of References Cited (PTO-892)
- 15) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 16) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) \_\_\_\_\_
- 17) ☐ Interview Summary (PTO-413) Paper No(s). \_\_\_\_\_
- 18) ☐ Notice of Informal Patent Application (PTO-152)
- 19) ☒ Other: *Fax Cover Sheet*.

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### **DETAILED ACTION**

**Please Note:** In an effort to enhance communication with our customers and reduce processing time, Group 1640 is running a Fax Response Program for Written Restriction Requirements. A dedicated Fax machine is in place to receive your responses. The Fax number is 703-305-3704. A Fax cover sheet is attached to this Office Action for your convenience. We encourage your participation in this Program. If you have any questions or suggestions please contact Paula Hutzell, Ph.D., Supervisory Patent Examiner at Paula.Hutzell@uspto.gov or 703-308-4310. Thank you in advance for allowing us to enhance our customer service. Please limit the use of this dedicated Fax number to responses to Written Restrictions.

### ***Election/Restrictions***

Restriction to one of the following inventions is required under 35 U.S.C. 121:

- I. Claims 1-11, 38-54, 62 and 118-120, drawn to isolated nucleic acid encoding hCalDAG-GEFI comprising SEQ ID NO: 3, a vector, a host cell, and a method of producing a protein, and an expression vector, classified in class 435, subclass 69.1.
- II. Claims 1-11, 38-54, 62 and 118-120, drawn to isolated nucleic acid encoding hCalDAG-GEFII comprising SEQ ID NO: 7, a vector, a host cell, and a method of producing a protein, and an expression vector, classified in class 435, subclass 69.1.
- III. Claims 1-11, 38-54, 62 and 118-120, drawn to isolated nucleic acid encoding mCalDAG-GEFI comprising SEQ ID NO: 16, a vector, a host cell, and a method of producing a protein, and an expression vector, classified in class 435, subclass 69.1.
- IV. Claims 1-11, 38-54, 62 and 118-120, drawn to isolated nucleic acid encoding rCalDAG-GEFI comprising SEQ ID NO: 5, a vector, a host cell, and a method of producing a protein, and an expression vector, classified in class 435, subclass 69.1.

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- V. Claims 1-11, 38-54, 62 and 118-120, drawn to isolated nucleic acid encoding hcAMP-GEF comprising SEQ ID NO: 18, a vector, a host cell, and a method of producing a protein, and an expression vector, classified in class 435, subclass 69.1.
- VI. Claims 1-11, 38-54, 62 and 118-120, drawn to isolated nucleic acid encoding rcAMP-GEFI comprising SEQ ID NO: 9, a vector, a host cell, and a method of producing a protein, and an expression vector, classified in class 435, subclass 69.1.
- VII. Claims 1-11, 38-54, 62 and 118-120, drawn to isolated nucleic acid encoding rcAMP-GEFII comprising SEQ ID NO: 15, a vector, a host cell, and a method of producing a protein, and an expression vector, classified in class 435, subclass 69.1.
- VIII. Claims 63-69, 116-117 and 124-126, drawn to a substantially pure hCalDAG-GEFI protein comprising SEQ ID NO: 4, and a pharmaceutical preparation of protein, classified in class 530, subclass 350.
- IX. Claims 63-69, 116-117 and 124-126, drawn to a substantially pure hCalDAG-GEFII protein comprising SEQ ID NO: 8, and a pharmaceutical preparation of protein, classified in class 530, subclass 350.
- X. Claims 63-69, 116-117 and 124-126, drawn to a substantially pure mCalDAG-GEF protein comprising SEQ ID NO: 17, and a pharmaceutical preparation of protein, classified in class 530, subclass 350.
- XI. Claims 63-69, 116-117 and 124-126, drawn to a substantially pure rCalDAG-GEF protein comprising SEQ ID NO: 6, and a pharmaceutical preparation of protein, classified in class 530, subclass 350.

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- XII. Claims 63-69, 116-117 and 124-126, drawn to a substantially pure hcAMP-GEF protein comprising SEQ ID NO: 19, and a pharmaceutical preparation of protein, classified in class 530, subclass 350.
- XIII. Claims 63-69, 116-117 and 124-126, drawn to a substantially pure rcAMP-GEFI protein comprising SEQ ID NO: 10, and a pharmaceutical preparation of protein, classified in class 530, subclass 350.
- XIV. Claims 63-69, 116-117 and 124-126, drawn to a substantially pure rcAMP-GEFII protein comprising SEQ ID NO: 16, and a pharmaceutical preparation of protein, classified in class 530, subclass 350.
  
- XV. Claims 72-75, 121-123 and 129-130, drawn to an antibody which binds to hCalDAG-GEFI, classified in class 530, subclass 387.1.
- XVI. Claims 72-75, 121-123 and 129-130, drawn to an antibody which binds to hCalDAG-GEFII, classified in class 530, subclass 387.1.
- XVII. Claims 72-75, 121-123 and 129-130, drawn to an antibody which binds to mCalDAG-GEF, classified in class 530, subclass 387.1.
- XVIII. Claims 72-75, 121-123 and 129-130, drawn to an antibody which binds to rCalDAG-GEF, classified in class 530, subclass 387.1.
- XIV. Claims 72-75, 121-123 and 129-130, drawn to an antibody which binds to hcAMP-GEF, classified in class 530, subclass 387.1.
- XX. Claims 72-75, 121-123 and 129-130, drawn to an antibody which binds to rcAMP-GEFI, classified in class 530, subclass 387.1.
- XXI. Claims 72-75, 121-123 and 129-130, drawn to an antibody which binds to rcAMP-GEFII, classified in class 530, subclass 387.1.

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XXII. Claims 70-71, drawn to a method of producing antibodies to hCalDAG-GEFI, classified in class 435, subclass 69.6.

XXIII. Claims 70-71, drawn to a method of producing antibodies to hCalDAG-GEFII, classified in class 435, subclass 69.6.

XXIV. Claims 70-71, drawn to a method of producing antibodies to mCalDAG-GEF, classified in class 435, subclass 69.6.

XXV. Claims 70-71, drawn to a method of producing antibodies to rCalDAG-GEF, classified in class 435, subclass 69.6.

XXVI. Claims 70-71, drawn to a method of producing antibodies to hcAMP-GEF, classified in class 435, subclass 69.6.

XXVII. Claims 70-71, drawn to a method of producing antibodies to rcAMP-GEFI, classified in class 435, subclass 69.6.

XXVIII. Claims 70-71, drawn to a method of producing antibodies to rcAMP-GEFII, classified in class 435, subclass 69.6.

XXIX. Claims 76-109 and 127-128, drawn to a method for identifying compounds which can modulate expression of hCalDAG-GEFI, classified in class 435, subclass 7.2.

XXX. Claims 76-109 and 127-128, drawn to a method for identifying compounds which can modulate expression of hCalDAG-GEFII, classified in class 435, subclass 7.2.

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XXXI. Claims 76-109 and 127-128, drawn to a method for identifying compounds which can modulate expression of mCalDAG-GEF, classified in class 435, subclass 7.2.

XXXII. Claims 76-109 and 127-128, drawn to a method for identifying compounds which can modulate expression of rCalDAG-GEF, classified in class 435, subclass 7.2.

XXXIII. Claims 76-109 and 127-128, drawn to a method for identifying compounds which can modulate expression of hcAMP-GEF, classified in class 435, subclass 7.2.

XXXIV. Claims 76-109 and 127-128, drawn to a method for identifying compounds which can modulate expression of rcAMP-GEFI, classified in class 435, subclass 7.2.

XXXV. Claims 76-109 and 127-128, drawn to a method for identifying compounds which can modulate expression of rcAMP-GEFII, classified in class 435, subclass 7.2.

XXXVI. Claims 12-27, 110-111 and 113-114, drawn to a method for identifying allelic variants of hCalDAG-GEFI, classified in class 435, subclass 6.

XXXVII. Claims 12-27, 110-111 and 113-114, drawn to a method for identifying allelic variants of hCalDAG-GEFII, classified in class 435, subclass 6.

XXXVIII. Claims 12-27, 110-111 and 113-114, drawn to a method for identifying allelic variants of mCalDAG-GEF, classified in class 435, subclass 6.

XXXIX. Claims 12-27, 110-111 and 113-114, drawn to a method for identifying allelic variants of rCalDAG-GEF, classified in class 435, subclass 6.

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- XL. Claims 12-27, 110-111 and 113-114, drawn to a method for identifying allelic variants of hcAMP-GEF, classified in class 435, subclass 6.
- XLI. Claims 12-27, 110-111 and 113-114, drawn to a method for identifying allelic variants of rcAMP-GEFI, classified in class 435, subclass 6.
- XLII. Claims 12-27, 110-111 and 113-114, drawn to a method for identifying allelic variants of rcAMP-GEFII, classified in class 435, subclass 6.
  
- XLIII. Claims 28-37, 110, 112 and 115, drawn to a method of identifying allelic variants of hCalDAG-GEFI with an antibody, classified in class 435, subclass 7.1.
- XLIV. Claims 28-37, 110, 112 and 115, drawn to a method of identifying allelic variants of hCalDAG-GEFII with an antibody, classified in class 435, subclass 7.1.
- XLV. Claims 28-37, 110, 112 and 115, drawn to a method of identifying allelic variants of mCalDAG-GEF with an antibody, classified in class 435, subclass 7.1.
- XLVI. Claims 28-37, 110, 112 and 115, drawn to a method of identifying allelic variants of rCalDAG-GEF with an antibody, classified in class 435, subclass 7.1.
- XLVII. Claims 28-37, 110, 112 and 115, drawn to a method of identifying allelic variants of hcAMP-GEF with an antibody, classified in class 435, subclass 7.1.
- XLVIII. Claims 28-37, 110, 112 and 115, drawn to a method of identifying allelic variants of rcAMP-GEFI with an antibody, classified in class 435, subclass 7.1.
- XLIX. Claims 28-37, 110, 112 and 115, drawn to a method of identifying allelic variants of rcAMP-GEFII with an antibody, classified in class 435, subclass 7.1.



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- L. Claims 55-61, drawn to a transgenic animal comprising hCalDAG-GEFI, classified in class 800, subclass 10.
- LI. Claims 55-61, drawn to a transgenic animal comprising hCalDAG-GEFII, classified in class 800, subclass 10.
- LII. Claims 55-61, drawn to a transgenic animal comprising mCalDAG-GEF, classified in class 800, subclass 10.
- LIII. Claims 55-61, drawn to a transgenic animal comprising rCalDAG-GEF, classified in class 800, subclass 10.
- LIV. Claims 55-61, drawn to a transgenic animal comprising hcAMP-GEF, classified in class 800, subclass 10.
- LV. Claims 55-61, drawn to a transgenic animal comprising rcAMP-GEFI, classified in class 800, subclass 10.
- LVI. Claims 55-61, drawn to a transgenic animal comprising rcAMP-GEFII, classified in class 800, subclass 10.

The inventions are distinct, each from the other because of the following reasons:

Inventions (I-VII), (VIII-XIV), (XV-XXI) and (L-LVI) are independent and distinct, each from the other, because they are products which possess characteristic differences in structure and function, and each has an independent utility, that is distinct for each invention which cannot be exchanged.

Inventions (XXII-XXVIII), (XXIX-XXXV), (XXXVI-XLII) and (XLIII-XLIX) are independent and distinct, each from the other, because the methods are practiced with materially different starting materials, have materially different process steps, and are for materially different purposes.

Inventions (XXII-XXVIII) and (XV-XXI) are related as process of making and product made. The inventions are distinct if either or both of the following can be shown: (1) that the

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process as claimed can be used to make other and materially different product or (2) that the product as claimed can be made by another and materially different process (MPEP § 806.05(f)). In the instant case the antibodies of invention (XV-XXI) can be made by recombinant protein engineering.

Inventions (VIII-XIV) and (XXIX-XXXV) are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the protein of invention (VIII-XIV) can be used for the production of antibodies.

Inventions (I-VII) and (XXXVI-XLII) are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the nucleic acid of invention (I-VII) can be used for the production of protein.

Inventions (VIII-XIV) and (XXII-XXVIII) are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the protein of invention (VIII-XIV) can be used for screening of compounds.

Inventions (XV-XXI) and (XLIII-XLIX) are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the antibody of invention (XV-XXI) can be used for immunoprecipitation.

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Invention (I-VII) is unrelated to inventions (XXII-XXVIII), (XXIX-XXXV) and (XLIII-XLIX). Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions are not disclosed as capable of use together.

Invention (VIII-XIV) is unrelated to inventions (XXXVI-XLII) and (XLIII-XLIX). Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions are not disclosed as capable of use together.

Invention (XV-XXI) is unrelated to inventions (XXIX-XXXV) and (XXXVI-XLII). Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions are not disclosed as capable of use together.

Invention (L-LVI) is unrelated to inventions (XXII-XXVIII), (XXIX-XXXV), (XXXVI-XLII) and (XLIII-XLIX). Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions are not disclosed as capable of use together.

Because these inventions are distinct for the reasons given above and have acquired a separate status in the art because of their recognized divergent subject matter and separate classification, restriction for examination purposes as indicated is proper.

Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the

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currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a petition under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

*Advisory Information*

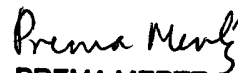
Any inquiry concerning this communication or earlier communications from the examiner should be directed to Joseph F. Murphy whose telephone number is 703-305-7245. The examiner can normally be reached on M-F 8:30-5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christina Chan can be reached on 703-308-3973. The fax phone numbers for the organization where this application or proceeding is assigned are 703-305-3014 for regular communications and 703-308-0294 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0196.



Joseph F. Murphy, Ph. D.  
Patent Examiner  
Art Unit 1644  
May 5, 2000



PREMA MERTZ  
PRIMARY EXAMINER



# RESTRICTION ELECTION FACSIMILE TRANSMISSION

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